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Award Number: W81XWH-06-1-0028

TITLE: NF Consortium Development Site: University of Alabama at Birmingham

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CONTRACTING ORGANIZATION: University of Alabama at Birmingham
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

University of Alabama at Birmingham has worked together with eight other consortium development sites and the Consortium Operations Center to develop the approach to develop innovative biologically based therapeutics for NF1 and to implement s equential hypothesis driven translation trials for multiple NF1 clinical manifestations. Dr. Korf has served as co chair of the p lexiform and other neurofibromas committee as well as chair of the publications committee. In addition, he serves as a membe r of the Operations Center. Several other UAB faculty serve on additional committees (Dr. Amy Theos plexiform and other n eurofibromas committee; Dr. Joseph Pressy MPNST committee; Dr. Alyssa Reddy visual pathway and other intracranial gliomas committee; Dr. Joseph Ackerson –
neurocognitive intervention committee). These efforts resulted in submission of a grant proposal to establish the NF1 Resear ch Consortium to the Department of Defense in August 2006.

15. SUBJECT TERMS
Neurofibromatosis Type 1: Planning grant

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INTRODUCTION:

The overall goal of the NF1 Consortium Development Award was to establish a consortium of nine clinical centers and an operations center with the goal of submitting a proposal to initiate collaborative clinical studies and therapeutic trials. University of Alabama at Birmingham was selected as one of the developmental sites, and, in addition, was selected as the operations center for the overall consortium. The developmental consortium has met its goals of designed two biologically-based therapeutic trials and submission of a full proposal to the Department of Defense to fund the execution of these trials.

BODY:

Task 1. Prepare for meeting of other development sites to plan consortium and award proposal (prior to meeting of development sites)

a. Develop internal communications system about project within UAB, including regular meetings of key and consulting personnel as well as regular e-mail updates
b. Initiate external communications system with other development sites (i.e., other institutions funded through this RFA)
c. Gather materials required to prepare for development site meeting in Baltimore
d. Participate in development site meeting

A team of professionals at UAB has been assembled and has actively participated in development of the NF Research Consortium. Weekly meetings of the core group, consisting of Drs. Bruce Korf, Alyssa Reddy, Amy Theos, and Ms. Bambi Burns (nurse) and Mr. Patrick Packer (study coordinator) are held. In addition, other UAB consultants have participated in specific committees of the consortium (see below). External communications have been established via e-mail and a web site through the Operations Center. The first consortium development meeting was held in Baltimore on November 14, 2005. At this meeting, in a session chaired by Dr. Korf, it was decided that the consortium would focus on four areas for the development of clinical trials: plexiform and other neurofibromas, visual pathway and other intracranial tumors, cognitive disorders, and malignant peripheral nerve sheath tumors. A follow-up meeting of the development site PIs was held in Atlanta on April 7, 2006.

Task 2. Work with other development sites to establish consortium and prepare submission of award proposal (following meeting and thereafter)

a. Implement on-site procedures for data management and administration
b. Establish mechanisms for local and Army IRB review of protocols
c. Contribute to formation of database and tissue distribution systems
d. Work with other centers to establish procedures and policies for consortium, including mechanisms of protocol management, disbursement of funds, intellectual and material rights, publication policy, etc.

e. Participate in discussions with study statistician
f. Gather any necessary documentary materials from UAB participants and research administration for submission of proposal

Working together with the consortium Operations Center and other development sites, a set of procedures have been implemented for data management, IRB review of protocols, data and tissue distribution systems, statistical analysis, and development of policies and procedures. All of these are described in detail in the full proposal to fund the consortium. The table below lists specific roles of personnel from UAB in the various consortium committees. In addition, Dr. Korf serves as co-investigator of the Operations Center, and therefore played a major role in development of the final proposal.

Investigator	**Committee**
Bruce R. Korf, M.D., Ph.D.	Chair, Publications Committee Co-chair, Plexiform & Other Neurofibromas Committee
Alyssa Reddy, M.D.	Visual Pathway & Other Intracranial Gliomas Committee
Amy Theos, M.D.	Plexiform & Other Neurofibromas Committee
Joseph Pressy, M.D.	Malignant Peripheral Nerve Sheath Tumors Committee
Joseph Ackerson, Ph.D.	Neurocognitive Intervention Committee
William Grizzle, M.D.	Malignant Peripheral Nerve Sheath Tumors Committee

KEY RESEARCH ACCOMPLISHMENTS:

- Established functional unit of clinical and research personnel at UAB to participate fully in clinical studies of NF1 Consortium
- Participated in all four consortium committees (plexiform & other neurofibromas, visual pathway and other intracranial gliomas, malignant peripheral nerve sheath tumors, and neurocognitive intervention)
- Participated in the development of two clinical trials put forward in the full proposal by the consortium to the Department of Defense

- Worked with the other developmental sites and Operations Center in all aspects of development of the consortium and writing the funding proposal to the Department of Defense

REPORTABLE OUTCOMES:

Full proposal submitted as planned

CONCLUSION:

During the past year, the nine developmental sites and Operations Center have worked together to formulate a consortium to perform collaborative clinical studies and clinical trials for patients with neurofibromatosis type 1. Two clinical trials have been put forward as the initial studies to be performed by the consortium, with two additional trials that will launch soon thereafter. This represents a major step forward in research on neurofibromatosis that will maximize our efforts to translate new research findings to clinical application rapidly and with maximum likelihood of achieving definitive results.

REFERENCES:

Not Applicable

APPENDICES:

Not Applicable

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

SUPPORTING DATA:

Not Applicable